

**SUBSTITUTE FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

Attorney Docket No: G1070-2
Applicant: Kenneth W. Batchelor, et al.
Filed: March 16, 1995
Title: ANDROSTENONE DERIVATIVE

Serial No: 08/405,120

Art Unit:

Examiner:

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub Class	Filing Date If Appropriate
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FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Country	Class	Sub Class	Translation Yes	No
BAQ	WO 92/16233	10/01/92	PCT	(gumley)	—		
BAR	WO 94/07909	04/14/94	PCT	(gumley)	—		
BAS	WO 94/03475	02/17/94	PCT	(gumley)	—		
BAT	WO 94/03476	02/17/94	PCT	(gumley)	—		
BAU	5-170789 A	12/1991	Japan		—		✓
BAV	WO 92/16213	10/01/92	PCT	(gumley)	—		
BAW	WO 93/23038	11/25/93	PCT	(gumley)	—		
BAX	WO 93/23039	11/25/93	PCT	—	—		
BAY	WO 93/23048	11/25/93	PCT	—	—		
BAZ	WO 93/23053	11/25/93	PCT	—	—		
BBA	WO 93/23050	11/25/93	PCT	—	—		
BBB	WO 93/23420	11/25/93	PCT	—	—		
BBC	WO 92/18132	10/29/92	PCT	(gumley)	—		
BBD	WO 93/23040	11/25/93	PCT	—	—		
BBE	WO 93/23041	11/25/93	PCT	—	—		
BBF	WO 93/23042	11/25/93	PCT	—	—		
BBG	WO 93/23419	11/25/93	PCT	—	—		
BBH	WO 93/23051	11/25/93	PCT	—	—		
BBI	WO 95/02607	01/26/95	PCT	—	—		

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Examiner Initial	Document Number	Author, Title, Date, Pertinent Pages, etc.
CAA	Stoner, E., "The Clinical Development of a 5 α -Reductase Inhibitor, Finasteride," <i>J. Steroid Biochem. Molec. Biol.</i> , 37 , No. 3, pp. 375-378, 1990	
CAB	van Velthuisen, J.A., et al., "Synthesis of (\pm)-N-Methyl-6-aza-8(14)-dehydro-19-nor-testosterone," <i>Tetrahedron Letters</i> , 27 , pp. 3081-3086, 1966	
CAC	Bhattacharya, A., et al., "Acylimidazolides as Versatile Synthetic Intermediates for the Preparation of Sterically Congested Amides and Ketones: A Practical Synthesis of Proscar," <i>Synthetic Communications</i> , 30 , No. 17, pp. 2683-2690, 1990	
CAD	Jones, D.R., et al., "Origin and Structure of Benign Prostatic Hyperplasia," <i>British Journal of Urology</i> , 66 , pp. 506-508, 1990	

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CAE	Kutney, J.P. and Johnson, R.A., "Synthesis of 6-Aza-Steroids: A Novel Class of Steroidal Hormones," <i>Chemistry and Industry</i> , pp. 1713-1714, October 1961	
CAF	Speckamp, W.N., et al., "Synthesis of N-Methyl- and N-Ethyl-6-Aza-8(14)-Dehydroestrone Methyl Ether," <i>Tetrahedron</i> , 24 , pp. 5881-5891, 1968	
CAG	Jacobs, T.L. and Brownfield, R.B., "The Introduction of Oxygen and Nitrogen into the B Ring of the Steroid Nucleus," pp. 4033-4039, August 1960	
CAH	Kutney, J.P., et al., "Synthesis of Ring A-Oxygenated 6-Aza Steroids," <i>Tetrahedron</i> , 24 , pp. 845-857, 1968	
CAI	Sampson, W.J., et al., "The Effects of 6-Azacholest-4-en-3 β -ol-7-one, an Inhibitor of Cholesterol 7 α -Hydroxylase, on Cholesterol Metabolism and Bile Acid Synthesis in Primary Cultures of Rat Hepatocytes," <i>Biochimica et Biophysica Acta</i> , 960 , pp. 268-274, 1988	
CAJ	Kutney, J.P., Synthesis of 6-Aza Steroids - A Novel Class of Azaandrostane Analogues," <i>Canadian J. of Chem.</i> , 41 , pp. 613-619, 1963	
CAK	Speckamp, W.N., et al., "Synthesis of N-Methyl-6-Aza-8(14)-Dehydro-19-Nor-Testosterone," <i>Tetrahedron</i> , 24 , pp. 5893-5898, 1968	
CAL	Imperato-McGinley, J., et al., "Androgens and the Evolution of Male-Gender Identity Among Male Pseudohermaphrodites with 5 α -Reductase Deficiency," <i>The New England J. of Med.</i> , 300 , No. 22, pp. 1233-1237, 1979	
CAM	Holt, D.A., et al., "Inhibition of Steroid 5 α -Reductase by 3-Nitrosteroids: Synthesis, Mechanism of Inhibition, and In Vivo Activity," <i>Bioorganic & Medicinal Chem. Letters</i> , 1 , No. 1, pp. 27-32, 1991	

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Examiner Initial	Document Number	
D. D. AUS	CAN	Holt, D.A., et al., "Synthesis of a Steroidal A Ring Aromatic Sulfonic Acid as an Inhibitor of Steroid 5 α -Reductase," <i>Steroids</i> , 56 , pp. 4-7, 1991
	CAO	Levy, M.A., et al., "Inhibition of Rat Liver Steroid 5 α -Reductase by 3-Androstene-3 Carboxylic Acids: Mechanism of Enzyme-Inhibitor Interaction," <i>Biochemistry</i> , 29 , No. 11, pp. 2815-2824, 1990
	CAP	Dupuy, G.M., et al., "Steroidal Inhibitors of Prostatic 5 α -Reductase: Structure-Activity Relationships," <i>Journal of Steroid Biochemistry</i> , 9 , pp. 1043-1047, 1978
	CAQ	Metcalf, B.W., et al., "Potent Inhibition of Human Steroid 5 α -Reductase (EC 1.3.1.30) by 3-Androstene-3-Carboxylic Acids," <i>Bioorganic Chemistry</i> , 17 , pp. 372-376, 1989
	CAR	Andersson, S., et al., "Deletion of Steroid 5 α -Reductase 2 Gene in Male Pseudo-hermaphroditism," <i>Nature</i> , 354 , pp. 159-161, 1991
	CAS	Thigpen, A.E., et al., "Molecular Genetics of Steroid 5 α -Reductase 2 Deficiency," <i>J. Clin. Invest.</i> , 90 , pp. 799-809, 1992
	CAT	Thigpen, A.E., et al., "Brief Report: The Molecular Basis of Steroid 5 α -Reductase Deficiency in a Large Dominican Kindred," <i>New England Jnl. of Med.</i> , 327 , No. 17, pp. 1216-1219, 1992
	CAU	Jenkins, E.P., "Genetic and Pharmacological Evidence for More Than One Human Steroid 5 α -Reductase," <i>J. Clin. Invest.</i> , 89 , pp. 293-300, 1992
CAV	Dave, V., et al., "Resolution of Conflicting Migratory Reports in Ring Expansion of 3-Keto Steroids to Oxygen and Nitrogen," <i>Canadian J. Chem.</i> , 58 , pp. 2666-2678, 1980	

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Examiner Initial	Document Number
CAW	Kobayashi, M., et al., "Reaction Products of 4-Aza- and 4-Methyl-4-azacholest-5-en-3-one with Nitrous Acid," <i>Chem. Pharm. Bull.</i> , 4 , No. 20, pp. 789-793, 1972
CAX	Narayanan, C.R., et al., "A Novel Reaction of Nitric Acid with Steroids," <i>Tetrahedron Letters</i> , No. 54, pp. 4703-4705, 1970
CAY	Chan, W.K., et al., "The Inhibition of 3 β HSD Activity in Porcine Granulosa Cells by 4-MA, a Potent 5 α -Reductase Inhibitor," <i>Biochem. Biophys. Res. Comm.</i> , 144 , no. 1, pp. 166-171, Apr 14, 1987
CAZ	Potts, G.O., et al., "Trilostane, an Orally Active Inhibitor of Steroid Biosynthesis," <i>Steroids</i> , 32 , no. 2, pp. 257-267, Sept 1978
CBA	Brandt, M. and Levy, M., "3 β -Hydroxy- Δ^5 -steroid Dehydrogenase/3-Keto- Δ^5 -steroid Isomerase from Bovine Adrenals: Mechanism of Inhibition by 3-Oxo-4-aza Steroids and Kinetic Mechanism of the Dehydrogenase," <i>Biochemistry</i> , 28 , pp. 140-148, 1989
CBB	Bhattacharya, A., et al., "Silylation-Mediated Oxidation of 4-Aza-3-ketosteroids with DDQ Proceeds via DDQ-Substrate Adducts," <i>J. Am. Chem. Soc.</i> , 110 , pp. 3318-3319, 1988
CBC	McConnell, J.D., "Medical Management of Benign Prostatic Hyperplasia with Androgen Suppression," <i>The Prostate Supplement</i> , 3 , pp. 49-50, 1990.

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D. Davis

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U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub Class	Filing Date If Appropriate
AA	5,278,159	01/11/94	Bakashi, et al.	546	77	
AB	5,318,961	06/07/94	Weintraub, et al.	546	77	
AC	5,342,948	08/30/94	Panzeri, et al.	546	77	
AD	5,380,728	01/10/95	Rasmusson	546	77	
AE	4,377,584	03/22/83	Rasmusson, et al.	546	77	
AF	5,017,568	05/21/91	Holt, et al.	574	123	
AG	5,110,939	05/05/92	Holt, et al.	548	252	
AH	4,882,319	11/21/89	Holt, et al.	514	25	

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Examiner Initial	Document Number	Date	Country	Class	Sub Class	Translation Yes	No
BA	WO 94/14833	07/07/94	PCT				
BB	WO93/13124	07/08/93	PCT				
BC	WO 91/12261	08/22/91	PCT				
BD	WO 94/07861	04/14/94	PCT				
BE	WO 94/11386	05/26/94	PCT				
BF	WO 94/11004	05/26/94	PCT				

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Examiner Initial	Document Number
CA	Ahmad, M.S. et al., "Beckmann Rearrangement of Some Steroid α -Hydroxy Ring B Ketoximes: 5-Oxo 5,6-Seco Nitriles," <i>Aust. J. Chem.</i> , 27 , pp. 1537-1543, 1974
CB	Hsia, S.L. and Voigt, W., "Inhibition of Dihydrotestosterone Formation: An Effective Means of Blocking Androgen Action in Hamster Sebaceous Gland," <i>Journal of Investigative Dermatology</i> , 62 , No. 3, pp. 224-227, 1974
CC	Holt, D.A., et al., "Steroidal A Ring Aryl Carboxylic Acids: A New Class of Steroid 5 α -Reductase Inhibitors," <i>J. Med. Chem.</i> , 33 , pp. 937-942, 1990
CD	Rasmusson, G.H., et al., "Azasteroids as Inhibitors of Rat Prostatic 5 α -Reductase," <i>J. Med. Chem.</i> , 27 , No. 12, pp. 1690-1701, 1984

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Examiner Initial	Document Number	Date	Name	Class	Sub Class	Filing Date If Appropriate
AI	5,098,908	03/24/92	Steinberg, et al.	546	77	
AJ	4,888,336	12/19/89	Holt, et al.	546	77	
AK	4,361,578	11/30/82	Alig, et al.	546	77	
AL	5,061,801	10/29/91	Williams, et al.	546	77	
AM	5,061,803	10/29/91	Williams	546	77	
AN	5,061,802	10/29/91	Steinberg, et al.	546	77	
AO	4,191,759	03/04/80	Johnston, et al.	514	75	
AP	4,937,237	06/26/90	Holt, et al.	546	77	
AQ	4,220,775	09/02/80	Rasmusson, et al.	546	77	
AR	4,954,446	09/04/90	Holt, et al.	435	101	

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BG	469 547 A2	07/30/91	Europe				
BH	200 859 A1	02/26/86	Europe				
BI	484 094 A2	10/29/91	Europe (Kojima)				
BJ	155 096 A2	02/20/85	Europe (Rasmusson)				
BK	314 199 A1	02/20/85	Europe (")				
BL	462 661 A2	06/14/91	Europe				
BM	462 665 A2	06/14/91	Europe				
BN	462 668 A2	06/14/91	Europe				

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(Including Author, Title, Date, Pertinent Pages, etc.)

Examiner Initial	Document Number	Date	Country	Class	Class	Yes	No
CE	Liang, T., et al., "Biochemical and Biological Studies with 4-AZA-Steroidal 5 α -Reductase Inhibitors," <i>J. Steroid Biochem.</i> , 19 , No. 1, pp. 385-390, 1983						
CF	House, H.O., "The Alkylation of Active Methylene Compounds," <i>Modern Synthetic Reactions</i> , 2d edition, pp. 492-570, The Benjamin/Cummings Publishing Co., 1972						
CG	Rosini, G. and Medici, A., "Cleavage of α -Hydroxy-ketoximes Under Mild Conditions Using Phosphonitrile Dichloride," <i>Communications</i> , pp. 665-666, October 1975						
CH	Hugl, H. and Zbiral, E., "Umsetzungen Von Δ^5 -Steroidolefinen Mit Pb(OAc) _{4-n} (N ₃) _n ," <i>Tetrahedron</i> , 29 , pp. 759-767, 1973						

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GROUP 12

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Examiner Initial	Document Number	Date	Name	Class	Sub Class	Filing Date If Appropriate
AS	5,041,433	08/20/91	Holt, et al.	514	176	
	4,910,226	03/20/90	Holt, et al.	514	573	
	4,814,324	03/21/89	Borris, et al.	514	26	
	4,317,817	03/02/82	Blohm, et al.			
	4,966,897	10/30/90	Angelastro, et al.	514	177	
AX	4,966,898	10/30/90	Angelastro, et al.	514	177	
AY	4,760,071	07/26/88	Rasmusson, et al.	574	284	

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Examiner Initial	Document Number	Date	Country	Class	Sub Class	Translation Yes	No
BO	473 225 A2	08/21/91	Europe				
	478 066 A2	09/18/91	Europe				
	473 226 A2	08/21/91	Europe				
	435 321 A2	12/28/90	Europe				
	469 548 A2	07/30/91	Europe				
BT	277 002 A2	01/27/88	Europe				
BU	004 949 A1	04/12/79	Europe				
BV	285 383 A2	03/30/88	Europe				
BW	271.219 A1	11/11/87	Europe				

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CI	Lazbin, I.M. and Koser, G.F., "Direct Conversion of Aliphatic Carboxamides to Alkylammonium Tosylates with [Hydroxy(tosyloxy)iodo]benzene," <i>J. Org. Chem.</i> , 51 , No. 14, pp. 2669-2671, 1986
CJ	Zbiral, E., et al., "Transferreaktionen Mit Hilfe Von Pb-IV-Acetat—IV ¹ ," <i>Tetrahedron</i> , 26 , pp. 1427-1434, 1970
CK	Zbiral, E. and Nestler, G., "Transferreaktionen Mit Hilfe Von Phenyl-Jodosoacetat—I ¹ " <i>Tetrahedron</i> , 26 , pp. 2945-2951, 1970
CL	Lettre, H., et al., "Verbesserung der Darstellung von 6-Aza-steroiden," <i>Liebigs Ann. Chem.</i> 703 , pp. 147-151, 1967
CM	Fieser, L.F. and Rajagopalan, S., "Selective Oxidation with N-Bromosuccinimide," Converse Memorial Laboratory, Cambridge 38, Massachusetts, June 1949

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BX	271 220 A1	11/11/87	Europe			
BY	428 366 A2	11/13/90	Europe			
BZ	414 491 A2	08/21/90	Europe			
BAA	414 490 A2	08/21/90	Europe			
BAB	462 664 A2	06/14/91	Europe			
BAC	462 662 A2	06/14/91	Europe			
BAD	285 382 A2	03/30/88	Europe			
BAE	052 799 A1	10/29/81	Europe			
BAF	414 529 A2	08/22/90	Europe			
BAG	375 345 A1	12/19/89	Europe			

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CN	Shoppee, C.W. and Roy, S.K., "Beckmann Rearrangement of Some α -Hydroxy-ketoximes," Dept. of Organic Chemistry, University of Sydney, Sydney, N.S.W., Australia, December 1962	
CO	Onda, M. and Takeuchi, K., "Alumina-Induced Reactions of Steroidal Oxime Acetates," <i>Chem. Pharm. Bull.</i> , 21 , No. 6, pp. 1287-1290, 1973	
CP	Staunton, J. and Eisenbraun, E.J., "3 β -Acetoxyetienic Acid," <i>Organic Syntheses</i> , pp. 8-11	
CQ	Suzuki, M., et al., "Palladium(0)-Catalyzed Reaction of α,β -Epoxy Ketones Leading to β -Diketones," <i>Journal of the American Chemical Society</i> , 102 , No. 6, pp. 2095-2096, March 12, 1980	
CR	Wallis, E.S. and Lane, J.F., "The Hoffmann Reaction," <i>Organic Reactions</i> , Chapter 7, Krieger Publishing Company, Malabar, Florida, 1975	
CS	Frye, S.V., et al., "6-Azasteroids: Potent Dual Inhibitors of Human Type 1 and 2 Steroid 5 α -Reductase," <i>Journal of Medicinal Chemistry</i> , 36 , No. 26, pp. 4313-4315, 1993	
CT	Frye, S.V., et al., "6-Azasteroids: Structure-Activity-Relationships for Inhibition of Type 1 and 2 Human 5 α -reductase and Human Adrenal 3 β -Hydroxy- Δ^5 -steroid Dehydrogenase/3-Keto- Δ^5 -steroid Isomerase," (full paper corresponding to reference CS)	

Not
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no publication
date

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	BAI 367 502 A1	10/26/89	Europe			
	BAJ 375 344 A1	12/19/89	Europe			
	BAK 375 347 A1	12/19/89	Europe			
	BAL 427 434 A2	10/29/90	Europe			
	BAM 298 652 A2	06/27/88	Europe			
	BAN 375 349 A1	12/19/89	Europe			
	BAO 375 351 A1	12/19/89	Europe			
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	CU Petrow, V., et al., "6-Methylene-4-Pregnen-3-Ones as Irreversible Inhibitors of Rat Prostatic Δ^4 -3 Ketosteroid 5 α -Reductase," <i>Steroids</i> , 38 , No. 2, pp. 121-140, 1981
	CV Robaire, B. et al., "Selective Inhibition of Rat Epididymal Steroid Δ^4 -5 α -Reductase by Conjugated Allenic 3-Oxo-5,10-Secosteroids," <i>Jrnl. of Steroid Biochemistry</i> , 8 , pp. 307-310, 1977
	CW Imperato-McGinley, J. and Gautier, T., "Inherited 5 α -Reductase Deficiency in Man," <i>TIG</i> , pp. 130-133, May 1986
	CX Brooks, J.R., et al., "5 α -Reductase Inhibitory and Anti-Androgenic Activities of Some 4-Azasteroids in the Rat," <i>Steroids</i> , 47 , pp. 1-19, January 1986
	CY Brown, L., et al., "The Synthesis of Some Cholesterol Derivatives as Probes for Mechanisms of Cholesterol Metabolism," <i>J. Chem. Soc.</i> , pp. 595-599, 1987
	CZ Rasmusson, G.H., et al., "Steroids: Structure-Activity Relationships for Inhibition of 5 α -Reductase and Androgen Receptor Binding," <i>J. Med. Chem.</i> , 29 , pp. 2298-2315, 1986

EXAMINER:

D. DAVIS

DATE CONSIDERED:

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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.